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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/594,236	09/25/2006	Yoshiko Ono	47232-5011	7379
55694 7590 08/10/2007 DRINKER BIDDLE & REATH (DC) 1500 K STREET, N.W. SUITE 1100 WASHINGTON, DC 20005-1209				
			EXAMINER BETTON, TIMOTHY E	
			ART UNIT 1614	PAPER NUMBER
			MAIL DATE 08/10/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/594,236

Applicant(s)

ONO ET AL.

Examiner

Timothy E. Betton

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>1 sheet, 25 September 2006</u> | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Claim Rejection-35 U.S.C. §112, 1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant specification cites subject matter directed toward sesamin and may also be applied for sesamin analogues. According to the invention, sesamin and its analogues are, for example, the dioxabicyclo [3.3.0] octane derivatives [...], and specific examples include sesamin, 15 sesaminol, episesamin, episesaminol, sesamolin, 2-(3,4- methylenedioxyphenyl)-6-(3-methoxy-4-hydroxyphenyl)-3,7-dioxabicyclo [3.3.0] octane, 2,6-bis (3-methoxy-4- hydroxyphenyl)-3,7-dioxabicyclo [3.3.0] octane, 2-(3,4-methylenedioxyphenyl)-6-(3-methoxy-4-hydroxyphenoxy)-3,7- 20 dioxabicyclo [3.3.0] octane, 2-(3,4-methylenedioxyphenyl)-6-(3,4-dihydroxyphenyl)-3,7-dioxabicyclo[3.3.0]octane, 2- (3-methoxy-4-hydroxyphenyl)-6-(3,4-dihydroxyphenyl)-3,7-dioxabicyclo[3.3.0]octane and 2,6-bis(3,4-dihydroxyphenyl)-3,dioxabicyclo[3.3.0]octane. There may also be utilized glucosides of sesamin and its analogues, as well as metabolites of sesamin and its analogues.

However, as disclosed above, there is no clarity as to which compounds are encompassed by the term 'analogue'. Additionally, there is no distinction or limitation in the instant claims to determine a practicing analogue of sesamin or episesamin in comparison to a general core moiety of sesamin or episesamin.

Claim Rejection-35 U.S.C. §101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 13-15 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd. App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

If the broadest reasonable interpretation of the claimed invention as a whole encompasses a human being, then a rejection under 35 U.S.C. 101 must be made indicating that the claimed invention is directed to nonstatutory subject matter.

Furthermore, the claimed invention must be examined with regard to all issues pertinent to patentability, and any applicable rejections under 35 U.S.C. 102, 103, or 112 must also be made. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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Claim Rejection-35 U.S.C. §112, 2nd paragraph

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 13-15 provide for the use of sesamin and/or episesamin, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 16-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Instant claims 16-20 are dependent upon claims 1, 2, 3, or 4 and define 'the use according to claim [...]'. However, claims 1-4 are all composition claims. As a result, it is unclear how instant claims 16-20 are intended to further limit claims 1-4. The instant specification does not conclude with said claims particularly adequately or distinctly claiming subject matter in the instant claims.

Claim Rejection- 35 USC § 103(a)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Forse et al. (USPN 5,397,778), Sumio et al. (JP 06227977 A) in view of Keizo et al. (JP 11246427 A) and Kengo et al. (JP 908268887 A).

For evidentiary purposes, sesamin specifically inhibits the increase in 5 desaturase at low concentrations. The gene expression of hepatic mitochondrial and peroxisomal fatty acid oxidation enzymes is also increased. Sesamin significantly decreases the hepatic lipogenic activity. (Jeng et al., Sesamin and Sesamol: Nature's Therapeutic Lignans, Current Enzyme Inhibition, 2005, 1, pp 11-20, especially p. 11, 3rd paragraph, p. 12, column 1, 1st paragraph, p. 12, column 2, lines 11 and 12)

Further, techniques are developed which separate human adipocytes by size. Microarray analysis is a well-known technique, which identifies large adipocyte cells as having markedly higher mRNA than small adipocyte cells. (Jernas et al., Separation of human adipocytes by size; hypertrophic by size: hypertrophic fat cells display distinct gene expression, The FASEB Journal. 2006; 20:1540-1542, printed pages 1-6, especially pages 1 and 2).

Thus, the instant claims disclose routine characterizations and properties distinct to sesamin and episesamin and, which are well-known to the skilled artisan. Sesamin and episesamin via their established mechanism of action generally induce an effect on small adipocytes, suppress the accumulation of TNF-alpha-producing enlarged adipocytes, and augmenting adiponectin.

Forse et al. teach saponin(s) containing enteral formulations for treatment of infection and inflammation. These saponin containing formulations are particularly useful in conjunction with oils rich in .omega.3 polyunsaturated fatty acids such as fish oils and flax oil but also show benefits with .omega.6 rich oils such as borage oil, black currant seed oil, canola oil and rapeseed oil. These formulations may also contain a lignan from the sesamin family.

In addition to teaching sesamin, Forse et al. also disclose episesamin (column 4, line 8).

Forse et al. teach the lowering of TNF-alpha via the administration of said agents comprising or consisting essentially of sesamin (column 6, lines 43-60).

Sumio et al. teach sesamin and/or episesamin as an active ingredient. A dose of sesamin and/or episesamin is preferably 1-100mg/day per adult daily in the case of oral administration. The purpose of claimed invention is to obtain the subject eliminating agent useful for treating ischemic reperfusion, inflammation, etc, capable of specifically catching and eliminating OH radicals, etc., having excellent safety, comprising sesamin as an active ingredient (Abstract).

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Keizo et al. teach sesamin and sesamol as safe ingredients contained in food thereby upon oral administration activates the metabolisms of saccharide and lipid. The activating agent is used for prophylaxis and/or treating diseases related to abnormal lipid metabolisms such as hyperlipidemia and hypertension (Abstract).

Kengo et al. teach the base octane derivative, dioxabicyclo, from which sesame oil is purified and isolated (sesamin and/or episesamin) (Abstract).

Thus, it would be *prima facie* obvious to the skilled artisan at the time of invention to at once recognize the reasonable expectation of success via the combining and incorporating together of Forse, Sumio, Keizo, and Kengo et al. The central issue of current invention is made obvious by the teachings of Forse et al., which describes embodiments drawn to sesamin and/or episesamin in association with lowering TNF-alpha. Sumio, Keizo et al., and Kengo et al. both support and suggest the motivation to combine with Forse et al. in view of subject invention. Sumio et al. teaches a specific regimen or system of oral administration. Keizo et al. teach the activation of the metabolisms of lipid. Kengo et al. teach the core structure or derivative thereof of sesamin. The skilled artisan would instantly be motivated to combine these said inventions together in view of the scope of claimed invention.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy E. Betton whose telephone number is (571) 272-9922. The examiner can normally be reached on Monday-Friday 8:30a - 5:00p.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TEB


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SUPERVISORY PATENT EXAMINER